

SPECIFICATIONS

Vendor shall supply instrumentation and reagent kit(s) to perform Hepatitis A, Hepatitis B and Hepatitis C testing.

TEST KITS

1. The assays must be FDA cleared for in vitro diagnostic use.
2. The assays are not CLIA waived rapid tests.
3. The assays shall detect the following analytes in serum or plasma.
 - Hepatitis B surface antibody
 - Hepatitis B surface antigen
 - Hepatitis B core antibody (total)
 - Hepatitis B core antibody IgM
 - Hepatitis C antibody
 - Hepatitis A IgM antibody
 - Hepatitis A IgG antibody

INSTRUMENTATION

1. The vendor must be able to provide reagent rental of the instruments for this contract at no additional charge to the Department of Health.
2. The vendor must provide instrument, computer, printer, software, consumables, reagents and service in the context of a single reagent rental contract for up to two (2) instruments. One instrument and accessories shall be supplied to the laboratory in Nashville with a second instrument tentatively scheduled for delivery at the Knoxville Branch Laboratory Location. Addresses are listed below.

Department of Health
Laboratory Services
630 Hart Lane
Nashville, TN 37216
Paula Gibbs
(615) 262-6364

Department of Health
Knoxville Regional Laboratory
2101 Medical Center Way
Knoxville, TN 37920
Vicki Lambert
(865) 549-5292

3. The instrument must be able to pull the required sample straight from the serum tube.
4. The instruments used to perform the Hepatitis assays must be able to analyze 200- 300 specimens per day for **each assay**.
5. The instrument must have the ability to transfer result data to the laboratory information management system (StarLims).
6. The instrument must have an onboard barcode reader.
7. The instrument software must have the ability to track the specimen barcode number and

identify if previously recorded.

8. Instrument shall track reactive results and perform duplicate assays prior to confirmation.
9. Instrument shall process and send repeat work list(s) to the instrument for analysis.
10. Instrument shall check assay results to see if they are final (repeat reactive) or require repeating (initially reactive).
11. Instrument shall operate on electrical power of 110 V.
12. Instrument shall have continuous, random access to reagents, samples and supplies.
13. Instrument shall have refrigerated reagent carousels with a minimum of 30 days onboard reagent stability.
14. Instrument must be capable of accepting various sizes of test tubes.
15. Instrument should have a non-bracketed control option for daily quality control.
16. Instrument shall have the capability of loading multiple assay test kits (HBsAg, HBsAb, HCV, etc.) for multiple analyte detection from the same specimen tube.

MAINTENANCE, TECHNICAL SUPPORT AND INSTALLATION

1. Vendor shall be responsible for all maintenance of leased instruments. Instruments shall be maintained according to the original manufacturer's maintenance standard. Instruments shall remain state of the art. The state shall not be responsible for replacement of instruments.
2. Vendor shall provide technical support from 8:00 AM to 4:30 PM CST.
3. Vendor shall provide a toll free phone number for technical support.
4. Vendor shall respond within 48 hours for on-site service and within one (1) hour of telephone technical support.
5. Vendor shall provide operation manual for each instrument.
6. Vendor shall provide on-site training for a minimum of two (2) laboratory personnel.
7. Vendor shall install instrument and accessories within 30 days to full operational status after award of contract.